EXHIBIT 42

JUN - 6 2006

510(K) SUMMARY

1. SUBMITTER

KAWASUMI LABORATORIES, INC.
3-28-15 Minami-Ohi
Shinagawa-Ku, Tokyo 140 Japan
PHONE: 81-3-376-1151
FAX: 81-3-376-3235
CONTACT: Mr. Kuroiwa

U.S. AGENT:

KAWASUMI LABORATORIES AMERICA, INC
4723 Oak Fair Blvd.
Tampa, FL 33610
PHONE: (813) 630-5554
FAX: (813) 630-5033
CONTACT: Mr. Jack Pavlo

2. NAME OF DEVICE: Kawasumi Laboratories Port Access Infusion Set with Antineedle Stick Protector
COMMON NAME: Port Access Infusion Set or Huber Needle Infusion Set
PROPRIETARY NAME: K-Shield Port Access Infusion Set
CLASSIFICATION: Class II, Codified at 21 CFR 880.5540.
PRODUCT CODE NUMBER: FPA

3. PREDICATE DEVICE: Exel Int Secure Touch Safety Huber Infusion Set

4. DESCRIPTION OF THE DEVICE: The Port Access Infusion Set with Antineedle Stick Protector is sterile, single use device with a non-coring Huber needle (90 degree), non-DEHP polyvinyl chloride tubing with or without Y connector or a needleless access connector which incorporates an integral antineedle stick protector used to prevent accidental needlestick injuries.

BASIC CONCEPT: The device is used for accessing an implanted medication port by puncturing the septum of the medication port and is used for the delivery of medication and for blood sampling. Fluid administration through the non-DEHP polyvinyl chloride fluid pathway of the port access infusion set are those generally used in hospitals and for delivery of chemotherapy. The device includes an integral antineedle stick device that when used prevent clinician's needle stick injuries

SIGNIFICANT PERFORMANCE CHARACTERISTICS: There are no new performance characteristics of this device compared to the substantially equivalent device marketed for sale in interstate commerce. Both deliver fluids to the vascular system through a non reactive material and provide an integral antineedle stick protector feature.

5. INTENDED USE: The Port Access Infusion Set with Antineedle Stick Protector is routinely used to access implanted medication ports for the delivery of medications. The device incorporates an integral antineedle stick protector used to prevent accidental needle stick injuries to the clinician.

6. TECHNOLOGICAL CHARACTERISTICS: There are no technological characteristics of this device to the substantially equivalent device from Kawasumi Laboratories being marketed for sale in interstate commerce.

7. PERFORMANCE DATA: Kawasumi Laboratories has conducted a successful simulated use study to determine the acceptability of this device for use to minimize accidental needlestick injuries. Also, Kawasumi Laboratories has conducted biocompatibility tests on the body fluid contacting material portions of the device and Kawasmi Laboratories believe that the results of these tests and the clinical evaluation show the device is suitable for its intended use.

8. CONCLUSIONS: The device meets all the biocompatibility and pyrogenicity test requirements. The Antineedle stick protector has successfully been clinically evaluated. Therefore, it is safe as the predicate device and performs as well as the predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2006

Kawasumi Laboratories, Incorporated
C/O Mr. Jack Pavlo
Authorized Representative
Kawasumi Laboratories America, Incorporated
4723 Oak Fair Boulevard
Tampa, Florida 33610

Re: K060580
Trade/Device Name: Kawasumi Laboratories Port Access Infusion Set with Antineedle Stick Protector
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: March 3, 2006
Received: March 8, 2006

Dear Mr. Pavlo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21. Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060580

EXHIBIT 40

# Indications for Use

510(k) Number (if known): K060580

Device Name: Kawasumi Laboratories Port Access Infusion Set with Antineedle Stick Protector

Indications For Use:

The Port Access Infusion Set with Antineedle Stick Protector is a safety intravascular administration set with a non-coring Huber needle that is used to access an implanted medication port for solution infusion and blood sampling. The port access infusion sets are designed with an integral antineedle stick protector that provides a safety feature intended to minimize accidental needle stick injuries when the needle is activated during removal from the patient's implanted medication port.

Prescription Use ___X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

[illegible] Radiology, General Hospital, [illegible] Dental Devices

510(k) Number K060580